

EPA Registration # 74530-23
After 5/27/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: 10/29/2012	EPA Reg No./File Symbol: 74530-23	Page 2 of 3			
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
63-4/ 830.6304	Odor	47193401	Helm Agro US, Inc.	Own	
63-5/ 830.7200	Melting Point	47170105	Helm Agro US, Inc.	Own	
63-7/ 830.7300	Density	47193401	Helm Agro US, Inc.	Own	
63-8/ 830.7840	Solubility	47193402 47170108	Helm Agro US, Inc.	Own	
63-9/ 830.7950	Vapour Pressure	47193403	Helm Agro US, Inc.	Own	
63-11/ 830.7550	Octanol/Water Partition Coefficient	47170106	Helm Agro US, Inc.	Own	
63-12/ 830.7000	pH	47193401	Helm Agro US, Inc.	Own	
63-13/ 830.6313	Stability	47170101	Helm Agro US, Inc.	Own	
63-14/ 830.6314	Oxidation/Reduction: Chemical incompatibility	47170101	Helm Agro US, Inc.	Own	
63-16/ 830.6316	Explosibility	47170101	Helm Agro US, Inc.	Own	
63-17/ 830.6317	Storage Stability	47890801	Helm Agro US, Inc.	Own	
63-20/ 830.6320	Corrosion Characteristics	47890801	Helm Agro US, Inc.	Own	
N/A/ 830.7000	UV/Visible Adsorption	47193401	Helm Agro US, Inc.	Own	

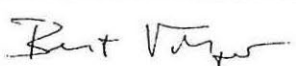


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Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1/ 870.1100	Acute Oral Toxicity - Rat	47170110	Helm Agro US	OWN	
81-2/ 870.1200	Acute Dermal Toxicity-Rabbit	47170111	Helm Agro US	OWN	
81-3/ 870.1300	Acute Inhalation Toxicity-Rat	47170112	Helm Agro US	OWN	
81-4/ 870.2400	Primary Eye Irritation-Rabbit	47170113	Helm Agro US	OWN	
81-5/ 870.2500	Primary Dermal Irritation-Rabbit	47170114	Helm Agro US	OWN	
81-6/ 870.2600	Dermal Sensitization in Guinea Pigs	47170115	Helm Agro US	OWN	
		EPA Company No			
	Generic Lambda-Cyhalothrin Data, offer to pay under "cite-all", see enclosed LOA from Syngenta dated 03/01/2011	100	Syngenta Crop Protection	Pay	
Signature 			Name and Title: Bert Volger, Ph.D. Agent for Helm Agro US, Inc.		Date October 29, 2012

2/5



LAMBDA-CYHALOTHRIN TC
FOR MANUFACTURING USE ONLY
In Formulating Insecticides

ACTIVE INGREDIENT:

% BY WT.

Lambda-cyhalothrin: [1 α (S*), 3 α (Z)]-(\pm)-cyano(3-Phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2 dimethylcyclopropanecarboxylate.....	97.9%
OTHER INGREDIENTS:.....	2.1%
TOTAL	100.0%

EPA Reg. No.74530-23

NET CONTENTS: 25 kg

EPA Est. No. 84365-CHN-001

KEEP OUT OF REACH OF CHILDREN
WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail).

ACCEPTED
MAY 27 2011

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 74530-23

U.S. DEPARTMENT OF AGRICULTURE
OFFICE OF PESTICIDE REGISTRATION
WASHINGTON, D.C. 20250
FEDERAL INSECTICIDE, FUNGICIDE,
AND RODENTICIDE ACT
REGISTRATION NO. 74530-23
LAMBDA-CYHALOTHRIN TC
FOR MANUFACTURING USE ONLY
IN FORMULATING INSECTICIDES

FIRST AID	
IF SWALLOWED	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment. For Chemical Emergencies: spill, leak, fire, exposure or accident, call CHEMTREC 24 hours a day 1-800-424-9300.	

Manufactured for:
 HELM AGRO US Inc.
 8275 Tournament Drive, Suite 340
 Memphis, TN, 38125
 info@helmagro.com

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and rubber gloves. Do not breathe dust or vapors. Wear a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P, or HE pre-filter. Prolonged or frequently repeated skin contact may result in allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and aquatic organisms and toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food, or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited

PESTICIDE STORAGE: Keep container closed when not in use. Do not use or store near heat or open flame. Store in original container and out of reach of children, preferably in a locked storage area. In case of spill or leak on floor or paved surfaces, soak up with sand, earth, or synthetic absorbent. Remove to chemical waste area.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide, Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

Nonrefillable Container: Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying.

Nonrefillable container equal to or less than 5 gallons: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Nonrefillable container equal to or less than 50 lbs.: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Nonrefillable container 5 gallons to bulk: Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Refillable containers 5 gallons to bulk: Refillable container: Refill this container with this pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

CONTAINER IS NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Formulators using this product are responsible for obtaining EPA registration for their formulated product.

Only for formulation into an insecticide for the following uses:

1. **Terrestrial & Aquatic Food:** Alfalfa; Brassica (head and stem); Canola; Corn (field, pop, seed and sweet); Cotton; Cucurbit Vegetables; Fruiting Vegetable Group; Garlic; Grass Forage, Fodder, and Hay; Legume Vegetable Group; Lettuce (head and leaf); Oat, Barley, Buckwheat and Rye; Onion (dry bulb); Peanuts; Pistachios; Pome Fruits Group; Rice and Wild Rice; Sorghum; Stone Fruit Group; Sugarcane; Sunflower; Tree Nut Group; Triticale and Wheat; Tuberous and Corm Vegetable Group.

Terrestrial Nonfood: Non crop lands (excluding public land); Tobacco (burley and flue-cured)

Forestry: Conifer and Deciduous trees (plantations, nurseries and seed orchards)

Domestic Indoor and Outdoor

Non-Domestic Indoor and Outdoor

Nonfood Greenhouse and Nurseries

2. Uses for which US-EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
3. Uses for experimental purposes that are in compliance with US-EPA requirements.

S/S

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Helm Agro US, Inc. or Seller. To the extent permitted by applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Helm and Seller harmless for any claims relating to such factors.

Helm warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law, this warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Helm, and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, HELM MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall Helm or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. To the extent permitted by applicable law, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF HELM AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF HELM OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Helm and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Helm.

EPA approved 02-18-2009 with comments incorporated; revised 11-03-2011 by adding additional crops

05/27/2011

1/5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 27 2011

Bert Volger
Consultant for Helm Agro US, Inc.
Ceres International LLC
1087 Heartsease Drive
West Chester, PA 19382

Subject: Application for Pesticide Amendment
Lambda-Cyhalothrin TC
EPA Reg. No. 74530-23
Your Submission Dated March 07, 2011
Decision No: 443458

Dear Volger:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez", written over a horizontal line.

Mark Suarez
Product Manager 13, Insecticide Branch
Registration Division (7504P)

Enclosure: Stamped label



HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

Via Courier Delivery
October 29, 2012

Document Processing Desk (RD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Mark Suarez
Registration Manager (PM-13)

Subject: Lambda-Cyhalothrin TC (EPA Reg.No.74530-23),
Amendment to registration: add an alternate source
Submission of PC data and CSF (Alternate Formulation 2)

Dear Mr. Suarez:

Helm Agro US Inc. is submitting this registration amendment for adding another alternate source to the current registration of Lambda-Cyhalothrin TC (EPA Reg. No. 74530-23). Based on the generated and enclosed product chemistry data (3 copies of each study report, see enclosed Bibliography of submitted studies), it has been demonstrated that the alternate source (Alternate Formulation 2) is very similar to the existing product (basic). There are no relevant changes in the manufacturing process and the product's identity. The identified impurities were determined at very low concentrations.

To facilitate this application, enclosed you will find the following documents:

1. EPA Form 8570-1
Executed Application for an Amendment of Pesticide Registration (Form 8570-1; OPP Identifier # 269582).
2. Bibliography of Submitted Studies
List of submitted studies (transmission letter).
3. Study Data
Three copies of Product Chemistry and Batch Analysis reports (total of 2 volumes).
4. Confidential Statement of Formula
One copy of the alternate Confidential Statement of Formula (CSF).
5. Certification with Respect to Citation of Generic Data
An executed EPA form 8570-34 with respect to citation of data.

6. Data Matrix (EPA form 8570-35)

One copy of the Data Matrix of all previously submitted data in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public File).

9. Registration Service Fee

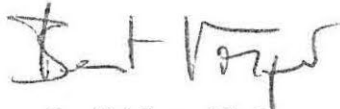
Under PRIA III, the subject application should be assigned EPA's Action Code R340: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source (Non-fast track; EPA decision review time of 4 months, fee = \$3,617).

10. Confirmation of PRIA fee payment

Agency Tracking ID: 74372391046 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this submission and approval of the subject application. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,



Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, TN 38125

Product(s): Lambda-Cyhalothrin Technical

EPA Registration No: 74530-23

Purpose of Submission: Submission of data in support of the application for an alternate CSF (Alternate #2) for Lambda-Cyhalothrin TC

Date of Submission: October 29, 2012

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Lambda-Cyhalothrin TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	HELM 121026	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	
2 of 2	Preliminary Analysis and Enforcement Analytical Method of Lambda-Cyhalothrin TGA1 (Validation of Analytical Methodology for the Assay of Active Ingredient and Related Impurities and Subsequent 5-Batch Analysis)	Nutrichemical Laboratory Company, Ltd. NC-2008-031	830.1700, 830.1750 and 830.1800	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 6, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-471494
EPA File Symbol or Registration Number: 74530-23
Product Name: LAMBDA-CYHALOTHRIN TC
EPA Receipt Date: 02-Nov-2012
EPA Company Number: 74530
Company Name: HELM AGRO US, INC.

BERT VOLGER, PH.D.
CERES INTERNATIONAL LLC
HELM AGRO US, INC.
1087 HEARTSEASE DRIVE
WEST CHESTER, PA 19382-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT;NON-FAST TRACK;REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. K.", is written over the typed name.

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{926321v~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 13

Receipt No.

S-

926321

EPA File Symbol/Reg. No.

74530-23

Pin-Punch Date:

11/2/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3,617

Technical & Impurities only - 55/11-08

Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: Steve Schaeble

Date: 11/5/12

Remarks:

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 11/2/12

Experts In-Processing Signature: [Signature] Date 11/6/12

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>74530-23</u>		EPA Receipt Date: <u>11/2/12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)				X	

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Studies submitted with this application package
passed PRN 11-03 review.

- Technical and impurities only, no inerts to review.

PRN 11-03 review - passed

Amendment - passed

SS/11-08-12

MRID-489855

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Receipt for Section 3

S: 926321

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No


Company: 74530 HELM AGRO US, INC. V


Risk Manager: Registration Division, Risk Management Team 13


Product #: 74530-23 Product Name: LAMBDA-CYHALOTHRIN TC


Override#:

Me Too Section3: 100-1013 Me Too Product Name: LAMBDA-CYHALOTHRIN TECHNICAL

Application Date: 29-Oct-2012 

OPP Rec'd Date: 02-Nov-2012 

Front End Date: 05-Nov-2012 

Risk Manager Send Date: 

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Study	
CSF	
<div> <div></div> <div></div> </div>	

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

CSF amendment

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

View/Edit

Online Payment

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 258F1844

Agency Tracking ID: 74372391046

Transaction Date and Time: 10/29/2012 12:33 EDT

Payment Summary

Address Information

Account Holder Name: Bert Volger
1087 Heartsease
Billing Address: Drive
Billing Address 2:
City: West Chester
State / Province: PA
Zip / Postal Code: 19382
Country: USA

Account Information

Card Type: Visa
Card Number: *****6411
Decision Number:
Registration Number: 74530-23
Helm Agro US
Company Name: Inc.
Company Number: 74530
Action Code: R340

Payment Information

Payment Amount: \$3,617.00
Transaction Date 10/29/2012
and Time: 12:33 EDT

Do you want to ☐ create a new plastic card?



48985500

HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

Via Courier Delivery

October 29, 2012

Document Processing Desk (RD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Mark Suarez
Registration Manager (PM-13)

Subject: Lambda-Cyhalothrin TC (EPA Reg.No.74530-23),
Amendment to registration: add an alternate source
Submission of PC data and CSF (Alternate Formulation 2)

Dear Mr. Suarez:

Helm Agro US Inc. is submitting this registration amendment for adding another alternate source to the current registration of Lambda-Cyhalothrin TC (EPA Reg. No. 74530-23). Based on the generated and enclosed product chemistry data (3 copies of each study report, see enclosed Bibliography of submitted studies), it has been demonstrated that the alternate source (Alternate Formulation 2) is very similar to the existing product (basic). There are no relevant changes in the manufacturing process and the product's identity. The identified impurities were determined at very low concentrations.

To facilitate this application, enclosed you will find the following documents:

1. EPA Form 8570-1
Executed Application for an Amendment of Pesticide Registration (Form 8570-1; OPP Identifier # 269582).
2. Bibliography of Submitted Studies
List of submitted studies (transmission letter).
3. Study Data
Three copies of Product Chemistry and Batch Analysis reports (total of 2 volumes).
4. Confidential Statement of Formula
One copy of the alternate Confidential Statement of Formula (CSF).
5. Certification with Respect to Citation of Generic Data
An executed EPA form 8570-34 with respect to citation of data.

6. Data Matrix (EPA form 8570-35)

One copy of the Data Matrix of all previously submitted data in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public File).

9. Registration Service Fee

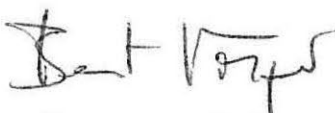
Under PRIA III, the subject application should be assigned EPA's Action Code R340: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source (Non-fast track; EPA decision review time of 4 months, fee = \$3,617).

10. Confirmation of PRIA fee payment

Agency Tracking ID: 74372391046 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this submission and approval of the subject application. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,

A handwritten signature in black ink, appearing to read "Bert Volger", with a stylized flourish at the end.

Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, TN 38125

Product(s): Lambda-Cyhalothrin Technical

EPA Registration No: 74530-23

Purpose of Submission: Submission of data in support of the application for an alternate CSF (Alternate #2) for Lambda-Cyhalothrin TC

Date of Submission: October 29, 2012

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Lambda-Cyhalothrin TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	HELM 121026	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	48985501
2 of 2	Preliminary Analysis and Enforcement Analytical Method of Lambda-Cyhalothrin TGAI (Validation of Analytical Methodology for the Assay of Active Ingredient and Related Impurities and Subsequent 5-Batch Analysis)	Nutrichemical Laboratory Company, Ltd. NC-2008-031	830.1700, 830.1750 and 830.1800	48985502



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
268582

Application for Pesticide - Section I

1. Company/Product Number 74530-23	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125 /Lambda-Cyhalothrin TC	PM# PM 13	
5. Name and Address of Application (Include ZIP Code) Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Amendment to existing registration: Application to add an alternate CSF (alternate #2); using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data) (Non-fast track; PRIA Code # R340, EPA decision review time of 4 months, fee = \$3,617);

EMAIL: bertvolger@comcast.net

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes", Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Bert Volger	Title Agent for HELM Agro US, Inc.	Telephone No. (Include Area Code) Phone: (610) 793-3222 Fax: (610) 793-1708	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Helm Agro US, Inc.		
4. Typed Name Bert Volger	5. Date October 29, 2012		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125 901-312-1525	EPA Registration Number/File Symbol 53883-23
Active Ingredient(s) and/or Representative Test Compound(s) Lambda-cyhalothrin	Date October 29, 2012
General Use Pattern(s) [list all those claimed for this product using 40 CFR Part 158] Indoor and Outdoor Uses	Product Name Lambda-Cyhalothrin TC

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: Method of Data Support (Check only one method)

☐ I am using the cite-all method of support and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). ☒ I am using the selective method of support (or cite-all option under the selective method) and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: General Offer-to-Pay

☒ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements] I hereby offer and agree to pay compensation to other persons with regard to the approval of this application to the extent required by FIFRA.

Section III: Certification

I hereby certify that this application for registration, this form for reregistration or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered: (i) to pay compensation to the extent required by Sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with Sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 10-29-2012	Typed or Printed Name and Title Bert Volger, Ph.D., Agent for Helm Agro US, Inc.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 10/29/2012

EPA Reg No./File Symbol: 74530-23

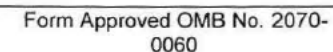
Page 1 of 3

Applicant's/Registrant's Name & Address: Helm Agro US, Inc.
8275 Tournement Drive, Suite 340
Memphis, TN 38125

Product: Lambda-Cyhalothrin TC

Ingredient: Lambda-Cyhalothrin Technical

Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	See submitted CSF
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	



DATA MATRIX

Page 2 of 3

Product: Lambda-Cyhalothrin TC

Ingredient:	Lambda-Cyhalothrin Technical
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[illegible]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form
Approved
OMB No.
2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: 10/29/2012		EPA Reg No./File Symbol: 74530-23		Page 3 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
		EPA Company No			
	[REDACTED]	[REDACTED]	[REDACTED]	Pay	
Signature: <i>Bert Volger</i>			Name and Title: Bert Volger, Ph.D. Agent for Helm Agro US, Inc.		Date October 29, 2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 06, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CERES INTERNATIONAL LLC
HELM AGRO US, INC.
1087 HEARTSEASE DRIVE
WEST CHESTER, PA 19382

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 02-NOV-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 926321

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 74530 HELM AGRO US, INC.

Risk Manager: Registration Division, Risk Management Team 13

Product #: 74530-23

Product Name: LAMBDA-CYHALOTHRIN TC

Override#:

Me Too Section3: 100-1013

Me Too Product Name: LAMBDA-CYHALOTHRIN TECHNICAL

Application Date: 29-Oct-2012

Front End Date: 05-Nov-2012

FFS Due Date:

OPP Target Date:

Fast Track:

Receipt Description: CSF amendment

Form A:

Signature Date:

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

V

OPP Rec'vd Date: 02-Nov-2012

Risk Manager Send Date:

Negotiated Due Date:

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Signature Date:

Form B:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

CSF

View/Edit



48985500

HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

Via Courier Delivery
October 29, 2012

Document Processing Desk (RD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Mark Suarez
Registration Manager (PM-13)

Subject: Lambda-Cyhalothrin TC (EPA Reg.No.74530-23),
Amendment to registration: add an alternate source
Submission of PC data and CSF (Alternate Formulation 2)

Dear Mr. Suarez:

Helm Agro US Inc. is submitting this registration amendment for adding another alternate source to the current registration of Lambda-Cyhalothrin TC (EPA Reg. No. 74530-23). Based on the generated and enclosed product chemistry data (3 copies of each study report, see enclosed Bibliography of submitted studies), it has been demonstrated that the alternate source (Alternate Formulation 2) is very similar to the existing product (basic). There are no relevant changes in the manufacturing process and the product's identity. The identified impurities were determined at very low concentrations.

To facilitate this application, enclosed you will find the following documents:

1. EPA Form 8570-1
Executed Application for an Amendment of Pesticide Registration (Form 8570-1; OPP Identifier # 269582).
2. Bibliography of Submitted Studies
List of submitted studies (transmission letter).
3. Study Data
Three copies of Product Chemistry and Batch Analysis reports (total of 2 volumes).
4. Confidential Statement of Formula
One copy of the alternate Confidential Statement of Formula (CSF).
5. Certification with Respect to Citation of Generic Data
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6. Data Matrix (EPA form 8570-35)

One copy of the Data Matrix of all previously submitted data in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public File).

9. Registration Service Fee

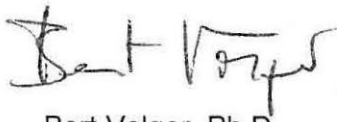
Under PRIA III, the subject application should be assigned EPA's Action Code R340: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source (Non-fast track; EPA decision review time of 4 months, fee = \$3,617).

10. Confirmation of PRIA fee payment

Agency Tracking ID: 74372391046 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this submission and approval of the subject application. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,

A handwritten signature in black ink, appearing to read "Bert Volger".

Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, TN 38125

Product(s): Lambda-Cyhalothrin Technical

EPA Registration No: 74530-23

Purpose of Submission: Submission of data in support of the application for an alternate CSF (Alternate #2) for Lambda-Cyhalothrin TC

Date of Submission: October 29, 2012

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Lambda-Cyhalothrin TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	HELM 121026	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	48985501
2 of 2	Preliminary Analysis and Enforcement Analytical Method of Lambda-Cyhalothrin TGAI (Validation of Analytical Methodology for the Assay of Active Ingredient and Related Impurities and Subsequent 5-Batch Analysis)	Nutrichemical Laboratory Company, Ltd. NC-2008-031	830.1700, 830.1750 and 830.1800	48985502



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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 10/29/2012			EPA Reg No./File Symbol: 74530-23		Page 1 of 3
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125			Product: Lambda-Cyhalothrin TC		
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/ 830.1550	Product Identity and Composition	47170101 48840501	Helm Agro US, Inc.	Own	
61-2/ 830.1600 & 830.1620	Beginning Materials and Manufacturing Process	47170101 48840501	Helm Agro US, Inc.	Own	
61-3/ 830.1670	Discussion of the Formation of Impurities	47170101 48840501	Helm Agro US, Inc.	Own	
62-1/ 830.1700	Preliminary Analysis	47170102 48840502	Helm Agro US, Inc.	Own	
62-2/ 830.1750	Certified Limits	47170101 48840501	Helm Agro US, Inc.	Own	See submitted CSF
62-3/ 830.1800	Enforcement Analytical Method	47170103 48840502	Helm Agro US, Inc.	Own	
63-2/ 830.6302	Color	47193401	Helm Agro US, Inc.	Own	
63-3/ 830.6303	Physical State	47193401	Helm Agro US, Inc.	Own	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 10/29/2012	EPA Reg No./File Symbol: 74530-23	Page 2 of 3			
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125	Product: Lambda-Cyhalothrin TC				
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
63-4/ 830.6304	Odor	47193401	Helm Agro US, Inc.	Own	
63-5/ 830.7200	Melting Point	47170105	Helm Agro US, Inc.	Own	
63-7/ 830.7300	Density	47193401	Helm Agro US, Inc.	Own	
63-8/ 830.7840	Solubility	47193402 47170108	Helm Agro US, Inc.	Own	
63-9/ 830.7950	Vapour Pressure	47193403	Helm Agro US, Inc.	Own	
63-11/ 830.7550	Octanol/Water Partition Coefficient	47170106	Helm Agro US, Inc.	Own	
63-12/ 830.7000	pH	47193401	Helm Agro US, Inc.	Own	
63-13/ 830.6313	Stability	47170101	Helm Agro US, Inc.	Own	
63-14/ 830.6314	Oxidation/Reduction: Chemical incompatibility	47170101	Helm Agro US, Inc.	Own	
63-16/ 830.6316	Explosibility	47170101	Helm Agro US, Inc.	Own	
63-17/ 830.6317	Storage Stability	47890801	Helm Agro US, Inc.	Own	
63-20/ 830.6320	Corrosion Characteristics	47890801	Helm Agro US, Inc.	Own	
N/A/ 830.7050	UV/Visible Adsorption	47193401	Helm Agro US, Inc.	Own	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

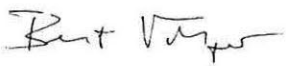


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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DATA MATRIX

Date: 10/29/2012		EPA Reg No./File Symbol: 74530-23		Page 3 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1/ 870.1100	Acute Oral Toxicity - Rat	47170110	Helm Agro US	OWN	
81-2/ 870.1200	Acute Dermal Toxicity-Rabbit	47170111	Helm Agro US	OWN	
81-3/ 870.1300	Acute Inhalation Toxicity-Rat	47170112	Helm Agro US	OWN	
81-4/ 870.2400	Primary Eye Irritation-Rabbit	47170113	Helm Agro US	OWN	
81-5/ 870.2500	Primary Dermal Irritation-Rabbit	47170114	Helm Agro US	OWN	
81-6/ 870.2600	Dermal Sensitization in Guinea Pigs	47170115	Helm Agro US	OWN	
		EPA Company No			
	Generic Lambda-Cyhalothrin Data, offer to pay under "cite-all", see enclosed LOA from Syngenta dated 03/01/2011	100	Syngenta Crop Protection	Pay	
Signature 			Name and Title: Bert Volger, Ph.D. Agent for Helm Agro US, Inc.		Date October 29, 2012

Decision Seq: 471494 Action Code: R340, AMENDMENT; NON-FAST TRACK; REVIEW WITHIN RD, E.C. ...

FFS Start Date: 23-Nov-2012 Tentative Ind: No Start/Stop Clock: FQPA Clock:

Due Date: 25-Mar-2013 75-Day Due Date: Days Elapsed:

OPP Target Due Dt: 21-Day Due Date: 23-Nov-2012 FFS Original Decision: ...

Negotiated Due Dt: 45-Day Due Date: 07-Jan-2013

Registrant: Response Due Date:

Current Status: PENDING (08-Nov-2012)

75 Day Letters 45/90 Day Screen Primary Decisions

FFS Negotiated Due Dates 12 OPP Target Due Date Decision Comments Payment Unmatched Payments

Decision Ownership Receipts Data Package Reduced Risk Meetings & Milestones FFS Information

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 926321	Banks, Melody	74530-23	25-Mar-2013	PENDING

Addition of new alternate source included product chemistry data

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Material Sent for Data Extraction

Reg. # 74530-23

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____

☒ New CSF(s) Dated 5/11/2012

☐ Other: _____

☒ Decision #: 465 360

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Melody Banks

Phone: (703) 305 5413 Division: RD/IB

Date: _____



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

OCT 25 2012

Bert Volger, PH.D
Ceres International, LLC
Helm Agro US, Inc.
1087 Heartsease Drive
West Chester, PA 19382

Dear Dr. Volger

Subject: Alternate Confidential Statement of Formula for a Manufacturing
Use Product
Lambda-Cyhalothrin TC
EPA Registration Number: 74530-23
Application Dated: May 11, 2012
Decision: 465-360

The Technical Review Branch of the Registration Division has completed their review of the proposed Alternate Confidential Statement of Formula dated May 11, 2012 and has determined it to be acceptable. This information has been placed in the file for the subject product.

If you have any questions please, contact Melody Banks on 703 305 5413 or E-mail at banks.melody@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Suarez", with a large, stylized flourish at the end.

Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division 7504P

Enclosure: Copy of Product Chemistry Review



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP Barcode No.: D403565 File Symbol No.: 74530-23 Decision No.: 465360
PC Code: 128897 Action Code: R 340
Food Use: NO Product Name: Lambda-Cyhalothrin TC

Date: October 24, 2012

SUBJECT: Product Chemistry Review of the Manufacturing Use Product Lambda-Cyhalothrin TC

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch/RD (7505P)
Registration Division (7505P)

Bruce F. Kitchens
24 Oct 2012
gfm 10/24/12

TO: RM #13, Mark Suarez/Samantha Hulkower
Insecticide Branch
Registration Division (7505P)

INTRODUCTION:

The registrant, Helm Agro US, Incorporated, is submitting a request to amend the registered manufacturing use product, Lambda-Cyhalothrin TC. This amendment is the result of an additional production site for the active ingredient. The active ingredient in this product is Lambda-Cyhalothrin at a label nominal concentration of 97.9% a.i. This product is intended for use in the manufacture of insecticide end-use products. In support of this request, the registrant has submitted an alternate Confidential Statement of Formula (CSF) dated 11 May 2012 and product chemistry data contained in MRID#s 488405-01 and 488405-02. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.
2. All impurities have been assayed and identified by the registrant. The registrant has not declared any impurities of toxicological concern in this product. All impurities have a nominal concentration and upper certified limits. The proposed alternate formulation contains fewer impurities than the current basic formulation.
3. The nominal concentration of the active ingredient listed on the proposed alternate CSF and the basic CSF are the same. The mean active ingredient nominal concentration as determined in the preliminary analysis is 98.10%. This differs from the active ingredient nominal concentration of 97.9% ai listed on the CSF; however, it does fall within the certified limits of the active ingredient.

DP Barcode No.: D403565

File Symbol No.: 74530-23

Decision No.: 465360

PC Code: 128897

Action Code: R 340

Food Use: NO

Product Name: Lambda-Cyhalothrin TC

4. The active ingredient's certified limits as proposed on the alternate CSF are acceptable.

5. The alternate production is:

[REDACTED]

In correspondence, the registrant declared that the manufacturing process did not change.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

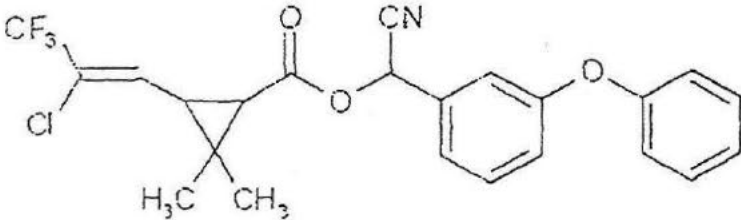
1. The proposed alternate formula CSF for the manufacturing use product, Lambda-Cyhalothrin dated 11 May 2012 is acceptable.
2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. This submission meets the criteria specified in 40 CFR 152.43 with respect to alternate formulations.

DP Barcode No.: D403565
PC Code: 128897
Food Use: NO

File Symbol No.: 74530-23
Action Code: R 340
Product Name: Lambda-Cyhalothrin TC

Decision No.: 465360

830.1550. Product Identity & Composition:

Trade Name:	Lambda-Cyhalothrin TC
Alternate Brand Name:	Lambda-Cyhalothrin Technical
Synonyms	R119321, PP321
EPA Registration No.:	74530- to be assigned
PC Code	128897
Source:	Alternate, new Source [REDACTED]
Common name (ISO):	Lambda-cyhalothrin (technical); ISO # 1750 (approved)
Chemical Name (IUPAC)	A reaction product comprising equal quantities of (S)- α -cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- α -cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
CAS Nomenclature:	[1a(S*),3a(Z)]-(\pm)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate
CAS Number:	91465-08-6
Molecular Weight	449.9
Identity test	GC (relative retention time), NMR, IR
Empirical Formula	C ₂₃ H ₁₉ ClF ₃ NO ₃
Structural Formula	
Purpose	Insecticide for Formulation Purposes only
Nominal Concentration / Label claim of active ingredient:	97.9% w/w
Other ingredients:	
Label statement:	2.1% w/w

DP Barcode No.: D403565
PC Code: 128897
Food Use: NO

File Symbol No.: 74530-23

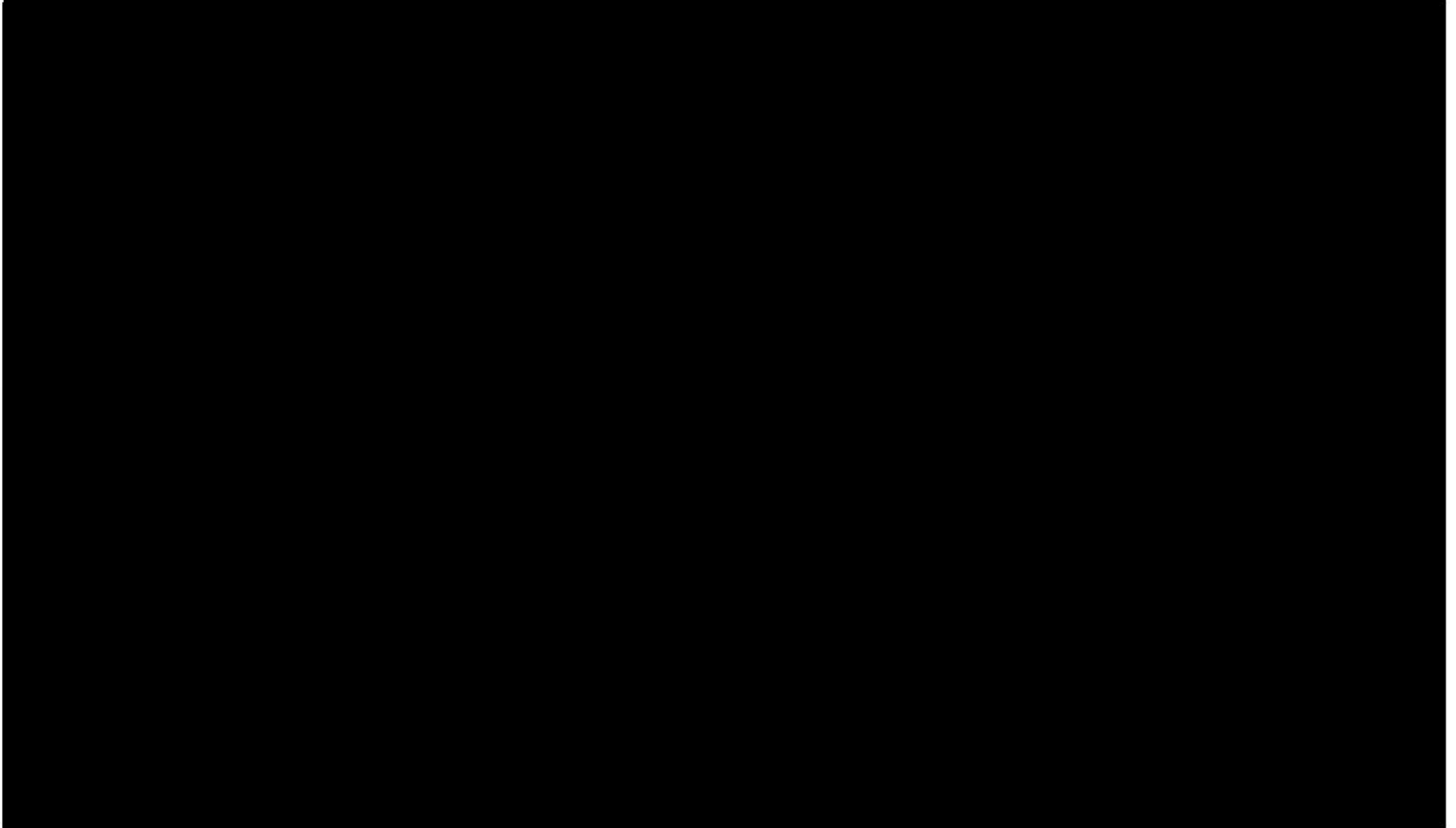
Action Code: R 340

Decision No.: 465360

Product Name: Lambda-Cyhalothrin TC

CONFIDENTIAL APPENDIX

Results of the 5 batch analysis are provided in the following table:



Manufacturing process information may be entitled to confidential treatment

5/15/12
science - science due date
on 5/15/2012

Fluxapyroxad- Summary of New PRIA Actions			
PRIA Code	Action	PRIA Date (science due date)	Comments
R350	PHI Change 7969-306, -309, -310, -311	2/27/2013 (10/30/12)	D 465948 DP 403787 (HED)
R 230	Outdoor, Non-food, Turf* 7969-GLN (Lexicon, combo), same as Priaxor, 7969-311 7969-GUO (Xzemplar, solo), same as Sercadis, 7969-309	9/27/2013 (3/31/2013)*	D 466140 DP 403943 (HED) DP 403944 (404971) (EFED) Golf courses, parks, sod, ... & *Residential uses (Public Participation)
R 190	New Food & Seed Uses PP# 2F8053 Seed uses: 7969-307, - 308	10/11/2013 (4/14/2013)	D 466686; D466679 DP 402912; DP 403828(HED) DP 404486, DP 403913 (EFED)
R190.1	7969-GLE (Xemium 703 ST, combo)	11/27/2013 (5/31/2013)	D 468140 DP 405413 (HED) DP 405412 (EFED)
R 295	Tolerances , Indirect Residues PP# 2F8058 7969-306, -309, -310, -311	11/6/2013 (7/9/2013)	D 466653 DP403993 (HED)

1. Beans/Data
-EFED requested info on non-target plant studies
2. "Bundling" : Which ones, HED/EFED coordination
3. Screening/ flags: any potential issues that will need to be addressed/prioritized in order to meet the PRIA timeline

DATA PACKAGE BEAN SHEET

Date: 18-Oct-2012

Page 1 of 2

Decision #: 465360

DP #: (403565)

PRIA

Parent DP #:

Submission #: 917574

E-Sub #:

*** Registration Information ***

Registration: 74530-23 - LAMBDA-CYHALOTHRIN TC

Company: 74530 - HELM AGRO US, INC.

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Samantha Hulkower SHULKOWE

Sent Date:

PRIA Due Date: 15-Oct-2012

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R340) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEME

Ingredients: 128897, lambda-Cyhalothrin(97.9%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 11-Jul-2012

Due Back:

DP Ingredient: 128897, lambda-Cyhalothrin

DP Title: Review of alternate source

CSF Included: ☒ Yes ☐ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 10-29-12
15-Sep-2012

Team Name: CHEM

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the data submitted to support the registration of an alternate source for the currently registered MUP.

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.7200/Melting point/melting range	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.7300/Density/relative density	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.7840/Water solubility: Column elution method, shake flask method	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.7950/Vapor pressure	Pass (20-Jun-2012)
48840502		Norris, D. (2012) Analysis of Five Batches of Lambda-Cyhalothrin Technical Material with Associated Validation, in Compliance with Good Laboratory Practice (Preliminary Analysis). Project Number: DNA1491. Unpublished study prepared by David Norris Analytical Laboratories, Ltd. 409p.	830.1700/Preliminary analysis	Pass (20-Jun-2012)
48840502		Norris, D. (2012) Analysis of Five Batches of Lambda-Cyhalothrin Technical Material with Associated Validation, in Compliance with Good Laboratory Practice (Preliminary Analysis). Project Number: DNA1491. Unpublished study prepared by David Norris Analytical Laboratories, Ltd. 409p.	830.1750/Certified limits	Pass (20-Jun-2012)
48840502		Norris, D. (2012) Analysis of Five Batches of Lambda-Cyhalothrin Technical Material with Associated Validation, in Compliance with Good Laboratory Practice (Preliminary Analysis). Project Number: DNA1491. Unpublished study prepared by David Norris Analytical Laboratories, Ltd. 409p.	830.1800/Enforcement analytical method	Pass (20-Jun-2012)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.1550/Product Identity and composition	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.1600/Description of materials used to produce the product	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.1650/Description of formulation process	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.1670/Discussion of formation of impurities	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.1750/Certified limits	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.1800/Enforcement analytical method	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6302/Color	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6303/Physical state	Pass (20-Jun-2012)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6304/Odor	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6314/Oxidizing or reducing action	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6315/Flammability	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6316/Explosibility	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6317/Storage stability	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6319/Miscibility	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.6321/Dielectric breakdown voltage	Pass (20-Jun-2012)
48840501		Volger, B. (2012) Lambda-Cyhalothrin TC (Technical): Product Identity and Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities, Certified Limits, Enforcement Analytical Method, Submittal of Sample. Project Number: HELM/120511. Unpublished study prepared by Ceres International, LLC. 131p.	830.7000/pH	Pass (20-Jun-2012)



HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

48840500

Via Courier Delivery

May 11, 2012

Document Processing Desk (RD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Mark Suarez
Registration Manager (PM -13)

Subject: Lambda-Cyhalothrin TC (EPA Reg.No.74530-23),
Amendment to registration: add an alternate source
Submission of PC data and CSF

Dear Mr. Suarez:

Helm Agro US Inc. is submitting this registration amendment for adding an alternate source to the current registration of Lambda-Cyhalothrin TC (EPA Reg. No. 74530-23). Based on the generated and enclosed product chemistry data (3 copies of each study report, see enclosed Bibliography of submitted studies), it has been demonstrated that the alternate source is very similar to the existing product (basic). There is no change in the manufacturing process. There is no significant change in the product's identity; actually there are fewer impurities than in the basic product, and the nominal concentration of the active ingredient has not changed.

To facilitate this application, enclosed you will find the following documents:

1. EPA Form 8570-1
Executed Application for an Amendment of Pesticide Registration (Form 8570-1; OPP Identifier # 269582).
2. Bibliography of Submitted Studies
List of submitted studies (transmission letter).
3. Study Data
Three copies of Product Chemistry and Batch Analysis reports (total of 2 volumes).
4. Confidential Statement of Formula
One copy of the alternate Confidential Statement of Formula (CSF).
5. Certification with Respect to Citation of Generic Data
An executed EPA form 8570-34 with respect to citation of data.

6. Data Matrix (EPA form 8570-35)

One copy of the Data Matrix of all previously submitted data in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public File).

9. Registration Service Fee

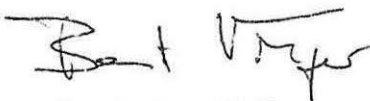
Under PRIA II, the subject application should be assigned EPA's Action Code R340: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source (Non-fast track; EPA decision review time of 4 months, fee = \$3,617).

10. Confirmation of PRIA fee payment

Pay.gov Tracking ID: 256KUI35; Agency Tracking ID: 74311485542 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this submission and approval of the subject application. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,



Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI



United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
269582

Application for Pesticide - Section I

1. Company/Product Number 74530-23	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125 /Lambda-Cyhalothrin TC	PM# PM 13	
5. Name and Address of Application (Include ZIP Code) Helm Agro US, Inc. 8295 Tournament Drive, Suite 310 Memphis, TN 38125 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Amendment to existing registration: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source) (Non-fast track; PRIA Code # R340, EPA decision review time of 4 months, fee = \$3,617);
EMAIL: bertvolger@comcast.net

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes", Unit Packaging wgt	No. per container
		If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Bert Volger	Title Agent for HELM Agro US, Inc.	Telephone No. (Include Area Code) Phone: (610) 793-1222 Fax: (610) 793-1708
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Helm Agro US, Inc.	
4. Typed Name Bert Volger	5. Date May 11, 2012	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125	EPA Registration Number/File Symbol 74530 - 23
Active Ingredient(s) and/or representative test compound(s) Lambda-Cyhalothrin	Date May 11, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Non Food, forestry, domestic in- and outdoor, non-domestic in-and outdoor, nurseries	Product Name Lambda - Cyhalothrin TC

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date May 11, 2012	Typed or Printed Name and Title Bert Volger, Agent for Helm Agro US, Inc.
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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 1 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/ 830.1550	Product Identity and Composition	47170101	Helm Agro US, Inc.	Own	
61-2/ 830.1600 & 830.1620	Beginning Materials and Manufacturing Process	47170101	Helm Agro US, Inc.	Own	
61-3/ 830.1670	Discussion of the Formation of Impurities	47170101	Helm Agro US, Inc.	Own	
62-1/ 830.1700	Preliminary Analysis	47170102	Helm Agro US, Inc.	Own	
62-2/ 830.1750	Certified Limits	47170101	Helm Agro US, Inc.	Own	See submitted CSF
62-3/ 830.1800	Enforcement Analytical Method	47170103	Helm Agro US, Inc.	Own	
63-2/ 830.6302	Color	47193401	Helm Agro US, Inc.	Own	
63-3/ 830.6303	Physical State	47193401	Helm Agro US, Inc.	Own	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 2 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
63-4/ 830.6304	Odor	47193401	Helm Agro US, Inc.	Own	
63-5/ 830.7200	Melting Point	47170105	Helm Agro US, Inc.	Own	
63-7/ 830.7300	Density	47193401	Helm Agro US, Inc.	Own	
63-8/ 830.7840	Solubility	47193402 47170108	Helm Agro US, Inc.	Own	
63-9/ 830.7950	Vapour Pressure	47193403	Helm Agro US, Inc.	Own	
63-11/ 830.7550	Octanol/Water Partition Coefficient	47170106	Helm Agro US, Inc.	Own	
63-12/ 830.7000	pH	47193401	Helm Agro US, Inc.	Own	
63-13/ 830.6313	Stability	47170101	Helm Agro US, Inc.	Own	
63-14/ 830.6314	Oxidation/reduction: Chemical incompatibility	47170101	Helm Agro US, Inc.	Own	
63-16/ 830.6316	Explosibility	47170101	Helm Agro US, Inc.	Own	
63-17/ 830.6317	Storage Stability	47890801	Helm Agro US, Inc.	Own	
63-20/ 830.6320	Corrosion Characteristics	47890801	Helm Agro US, Inc.	Own	
N/A/ 830.7050	UV/Visible Absorption	47193401	Helm Agro US, Inc.	Own	

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Approved
OMB No.
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DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 3 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1/ 870.1100	Acute Oral Toxicity - Rat	47170110	Helm Agro US	OWN	
81-2/ 870.1200	Acute Dermal Toxicity-Rabbit	47170111	Helm Agro US	OWN	
81-3/ 870.1300	Acute Inhalation Toxicity-Rat	47170112	Helm Agro US	OWN	
81-4/ 870.2400	Primary Eye Irritation-Rabbit	47170113	Helm Agro US	OWN	
81-5/ 870.2500	Primary Dermal Irritation-Rabbit	47170114	Helm Agro US	OWN	
81-6/ 870.2600	Dermal Sensitization in Guinea Pigs	47170115	Helm Agro US	OWN	
		EPA Company No			
	Generic Lambda-Cyhalothrin Data, offer to pay under "cite-all", see enclosed LOA from Syngenta dated 03/01/2011	100	Syngenta Crop Protection	Pay	
Signature		Name and Title: Bert Volger, Ph.D. Agent for Helm Agro US, Inc.		Date May 11, 2012	

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, TN 38125

Product(s): Lambda-Cyhalothrin Technical

EPA Registration No: 74530-23

Purpose of Submission: Submission of data in support of the application for an alternate CSF for Lambda-Cyhalothrin TC

Date of Submission: May 11, 2012

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Lambda-Cyhalothrin TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	HELM 120511	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	48840501
2 of 2	Analysis of Five Batches of Lambda-Cyhalothrin Technical Material with Associated Validation, in Compliance with Good Laboratory Practice (Preliminary Analysis)	David Norris Analytical Laboratories DNA1491	830.1700, 830.1750 and 830.1800	48840502



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP Barcode No.: D403565
PC Code: 128897
Food Use: NO

File Symbol No.: 74530-23
Action Code: R 340
Product Name: Lambda-Cyhalothrin TC

Decision No.: 465360

Date: October 24, 2012

SUBJECT: Product Chemistry Review of the Manufacturing Use Product Lambda-Cyhalothrin TC

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch/RD (7505P)
Registration Division (7505P)

Bruce F. Kitchens
24 Oct 2012

TO: RM #13, Mark Suarez/Samantha Hulkower
Insecticide Branch
Registration Division (7505P)

SRM 10/24/12

INTRODUCTION:

The registrant, Helm Agro US, Incorporated, is submitting a request to amend the registered manufacturing use product, Lambda-Cyhalothrin TC. This amendment is the result of an additional production site for the active ingredient. The active ingredient in this product is Lambda-Cyhalothrin at a label nominal concentration of 97.9% a.i. This product is intended for use in the manufacture of insecticide end-use products. In support of this request, the registrant has submitted an alternate Confidential Statement of Formula (CSF) dated 11 May 2012 and product chemistry data contained in MRID#s 488405-01 and 488405-02. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.
2. All impurities have been assayed and identified by the registrant. The registrant has not declared any impurities of toxicological concern in this product. All impurities have a nominal concentration and upper certified limits. The proposed alternate formulation contains fewer impurities than the current basic formulation.
3. The nominal concentration of the active ingredient listed on the proposed alternate CSF and the basic CSF are the same. The mean active ingredient nominal concentration as determined in the preliminary analysis is 98.10%. This differs from the active ingredient nominal concentration of 97.9% ai listed on the CSF; however, it does fall within the certified limits of the active ingredient.

DP Barcode No.: D403565
PC Code: 128897
Food Use: NO

File Symbol No.: 74530-23
Action Code: R 340
Product Name: Lambda-Cyhalothrin TC

Decision No.: 465360

4. The active ingredient's certified limits as proposed on the alternate CSF are acceptable.
5. The alternate production is:



In correspondence, the registrant declared that the manufacturing process did not change.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The proposed alternate formula CSF for the manufacturing use product, Lambda-Cyhalothrin dated 11 May 2012 is acceptable.
2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. This submission meets the criteria specified in 40 CFR 152.43 with respect to alternate formulations.

Product ingredient source information may be entitled to confidential treatment

DP Barcode No.: D403565

PC Code: 128897

Food Use: NO

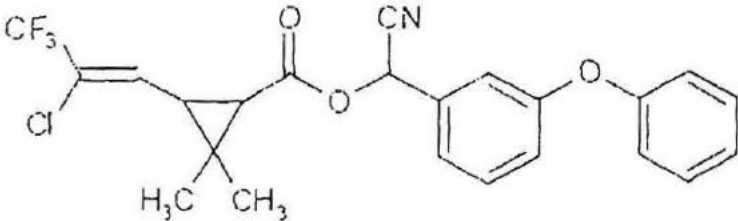
File Symbol No.: 74530-23

Action Code: R 340

Product Name: Lambda-Cyhalothrin TC

Decision No.: 465360

830.1550. Product Identity & Composition:

Trade Name:	Lambda-Cyhalothrin TC
Alternate Brand Name:	Lambda-Cyhalothrin Technical
Synonyms	R119321, PP321
EPA Registration No.:	74530- to be assigned
PC Code	128897
Source:	Alternate, new Source [REDACTED]
Common name (ISO):	Lambda-cyhalothrin (technical); ISO # 1750 (approved)
Chemical Name (IUPAC)	A reaction product comprising equal quantities of (S)- <i>a</i> -cyano-3-phenoxybenzyl (Z)-(1 <i>R</i> ,3 <i>R</i>)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- <i>a</i> -cyano-3-phenoxybenzyl (Z)-(1 <i>S</i> ,3 <i>S</i>)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
CAS Nomenclature:	[1 <i>a</i> (<i>S</i> [*]),3 <i>a</i> (<i>Z</i>)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate
CAS Number:	91465-08-6
Molecular Weight	449.9
Identity test	GC (relative retention time), NMR, IR
Empirical Formula	C ₂₃ H ₁₉ ClF ₃ NO ₃
Structural Formula	
Purpose	Insecticide for Formulation Purposes only
Nominal Concentration / Label claim of active ingredient:	97.9% w/w
Other ingredients:	
Label statement:	2.1% w/w

Product ingredient source information may be entitled to confidential treatment

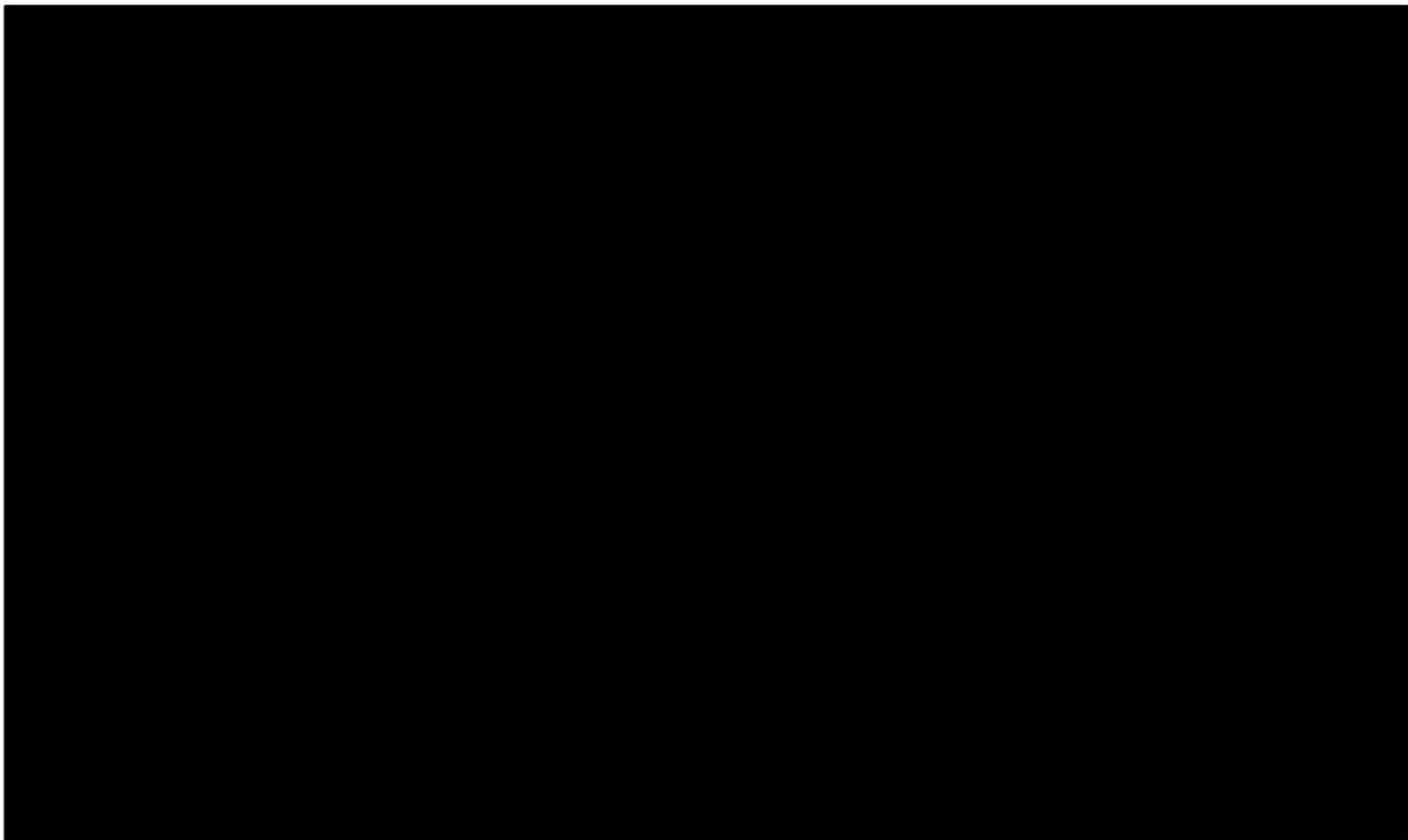
DP Barcode No.: D403565
PC Code: 128897
Food Use: NO

File Symbol No.: 74530-23
Action Code: R 340
Product Name: Lambda-Cyhalothrin TC

Decision No.: 465360

CONFIDENTIAL APPENDIX

Results of the 5 batch analysis are provided in the following table:



Manufacturing process information may be entitled to confidential treatment

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 5-25-12

Experts In-Processing Signature: MF Harrington Date 5-29-12 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>74530-23</u>		EPA Receipt Date: <u>5-25-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) <u>NO INERTS</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			X
	a) List study (or studies) not included with application			

Comments:

REGISTRANT CONTACTED REGARDING MISSING STUDY PAGES. ISSUES
HAVE BEEN RESOLVED. AA 6/8/12

TECHNICAL & IMPURITIES, NO INERTS TO REVIEW. AA 6/8/12 /JB

STUDIES PASS 11-3 REVIEW. AA 6/8/12

MRID - 488405

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Decision Information for 74530-23

Decision Seq: 465360
Action Code: R340, NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTI)

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

FFS Start Date: 15-Jun-2012
Tentative Ind: No
FFS Original Decision:

Due Date: 15-Oct-2012
75-Day Due Date:
FFS EUP Decision:

OPP Target Due Dt:
21-Day Screen Dt: 15-Jun-2012
FFS Primary Decision:

Negotiated Due Dt:
Start/Stop Clock
FQPA Clock:

Registrant:
Response Due Date:
Days Elapsed:

Current Status: PENDING (29-May-2012)

Decision Comments

Payment

Unmatched Payments

75 Day Letters

Meetings & Milestones

FFS Information

FFS Negotiated Due Dates

OPP Target Due Date

Decision Ownership

Receipts

Data Package

Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 917574	Hulkower, Samantha	74530-23	15-Oct-2012	PENDING

Addition of new alternate source includes Prod Chem data

Viewing Record 1 of 1

465360

DP 403565

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 6-15-12

Document Part Of: 74530-23
MRID, If Any: 488405

Content Screen: Recommended to
Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

Stephen Schauble



RE: Regarding Amendment to 74530-23 (Lambda-Cyhalothrin TC)

bert volger to: Anthony Ashe

06/08/2012 10:08 AM

Hi Anthony,

Attached you will find the missing page 75 of Volume 1. Please let me know, if this pdf version will work.

Sorry for the inconvenience this might have caused.

Thanks,

Bert

Bert Volger, Ph.D.
Ceres International LLC
1087 Heartsease Drive
West Chester, PA 19382
T 610-793-3222
bertvolger@ceresinternational.com

From: Anthony Ashe [mailto:Ashe.Anthony@epamail.epa.gov]

Sent: Friday, June 08, 2012 8:00 AM

To: bertvolger@comcast.net

Subject: Regarding Amendment to 74530-23 (Lambda-Cyhalothrin TC)

Good Morning,

This message is being sent regarding an issue with Volume 1 of the studies submitted in support of the above-mentioned amendment. Page 75 appears to have been omitted from the submitted copy. If this is simply a pagination issue, I can place a page 75 in the study which says "page intentionally left blank" and process the package. If page 75 does in fact exist, please submit a copy of that page for me to add to each study. You can deliver the page via fax (703-305-5060) or via email. Thank you for your help with this matter, and feel free to contact me with any questions you may have.

Best Regards,

Anthony H Ashe
MacFadden Contractor



(703)305-0073Lambda TC Vol 1 CA page 75 of 118.pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 29, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-465360
EPA File Symbol or Registration Number: 74530-23
Product Name: LAMBDA-CYHALOTHRIN TC
EPA Receipt Date: 25-May-2012
EPA Company Number: 74530
Company Name: HELM AGRO US, INC.

BERT VOLGER, PH.D.
CERES INTERNATIONAL LLC
HELM AGRO US, INC.
1087 HEARTSEASE DRIVE
WEST CHESTER, PA 19382-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. j. h.", is written below the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{917574C~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 13

Receipt No.

S- 917574

EPA File Symbol/Reg. No.

74530-23

Pin-Punch Date:

5/25/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R340

Granted:

R340

Amount Due: \$ 3,612.⁰⁰

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:



Date: 5-25-12

Remarks:

Receipt for Section 3

S: 917574

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 74530 HELM AGRO US, INC.

V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 74530-23

Product Name: LAMBDA-CYHALOTHRIN TC

Override#:

Me Too
Section3: 100-1013

Me Too
Product Name: LAMBDA-CYHALOTHRIN TECHNICAL

Application Date: 11-May-2012



OPP Rec'd Date: 25-May-2012



Front End Date: 29-May-2012



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Study	
CSF	
<div> <div></div> <div></div> <div></div> </div>	

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Submission of PC data and CSF

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

View/Edit



HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

48840500

Via Courier Delivery

May 11, 2012

Document Processing Desk (RD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Mark Suarez
Registration Manager (PM -13)

Subject: Lambda-Cyhalothrin TC (EPA Reg.No.74530-23),
Amendment to registration: add an alternate source
Submission of PC data and CSF

Dear Mr. Suarez:

Helm Agro US Inc. is submitting this registration amendment for adding an alternate source to the current registration of Lambda-Cyhalothrin TC (EPA Reg. No. 74530-23). Based on the generated and enclosed product chemistry data (3 copies of each study report, see enclosed Bibliography of submitted studies), it has been demonstrated that the alternate source is very similar to the existing product (basic). There is no change in the manufacturing process. There is no significant change in the product's identity; actually there are fewer impurities than in the basic product, and the nominal concentration of the active ingredient has not changed.

To facilitate this application, enclosed you will find the following documents:

1. EPA Form 8570-1
Executed Application for an Amendment of Pesticide Registration (Form 8570-1; OPP Identifier # 269582).
2. Bibliography of Submitted Studies
List of submitted studies (transmission letter).
3. Study Data
Three copies of Product Chemistry and Batch Analysis reports (total of 2 volumes).
4. Confidential Statement of Formula
One copy of the alternate Confidential Statement of Formula (CSF).
5. Certification with Respect to Citation of Generic Data
An executed EPA form 8570-34 with respect to citation of data.

6. Data Matrix (EPA form 8570-35)

One copy of the Data Matrix of all previously submitted data in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public File).

9. Registration Service Fee

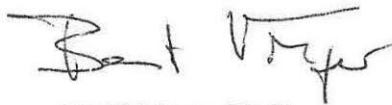
Under PRIA II, the subject application should be assigned EPA's Action Code R340: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source (Non-fast track; EPA decision review time of 4 months, fee = \$3,617).

10. Confirmation of PRIA fee payment

Pay.gov Tracking ID: 256KUI35; Agency Tracking ID: 74311485542 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this submission and approval of the subject application. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,

A handwritten signature in black ink, appearing to read "Bert Volger".

Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, TN 38125

Product(s): Lambda-Cyhalothrin Technical

EPA Registration No: 74530-23

Purpose of Submission: Submission of data in support of the application for an alternate CSF for Lambda-Cyhalothrin TC

Date of Submission: May 11, 2012

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Lambda-Cyhalothrin TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	HELM 120511	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	48840501
2 of 2	Analysis of Five Batches of Lambda-Cyhalothrin Technical Material with Associated Validation, in Compliance with Good Laboratory Practice (Preliminary Analysis)	David Norris Analytical Laboratories DNA1491	830.1700, 830.1750 and 830.1800	48840502



United States
Environmental Protection Agency
Washington, DC 20460

☐ Re-registration
☒ Amendment
☐ Other

OPP Identifier Number
269582

Application for Pesticide - Section I

1. Company/Product Number 74530-23	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125 /Lambda-Cyhalothrin TC	PM# PM 13	
5. Name and Address of Application (Include ZIP Code) Helm Agro US, Inc. 8295 Tournament Drive, Suite 310 Memphis, TN 38125 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:	

Section - II

☒ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____

☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application.

☐ Notification - Explain below. ☒ Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Amendment to existing registration: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source) (Non-fast track; PRIA Code # R340, EPA decision review time of 4 months, fee = \$3,617);
EMAIL: bertvolger@comcast.net

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes", Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Bert Volger	Title Agent for HELM Agro US, Inc.	Telephone No. (Include Area Code) Phone: (610) 793-3222 Fax: (610) 793-1708
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for HELM Agro US, Inc.	
4. Typed Name Bert Volger	5. Date May 11, 2012	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125	EPA Registration Number/File Symbol 74530 - 23
Active Ingredient(s) and/or representative test compound(s) Lambda-Cyhalothrin	Date May 11, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Non Food, forestry, domestic in- and outdoor, non-domestic in-and outdoor, nurseries	Product Name Lambda - Cyhalothrin TC

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date May 11, 2012	Typed or Printed Name and Title Bert Volger, Agent for Helm Agro US, inc.
---------------	----------------------	------------------------------------------------------------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 1 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/ 830.1550	Product Identity and Composition	47170101	Helm Agro US, Inc.	Own	
61-2/ 830.1600 & 830.1620	Beginning Materials and Manufacturing Process	47170101	Helm Agro US, Inc.	Own	
61-3/ 830.1670	Discussion of the Formation of Impurities	47170101	Helm Agro US, Inc.	Own	
62-1/ 830.1700	Preliminary Analysis	47170102	Helm Agro US, Inc.	Own	
62-2/ 830.1750	Certified Limits	47170101	Helm Agro US, Inc.	Own	See submitted CSF
62-3/ 830.1800	Enforcement Analytical Method	47170103	Helm Agro US, Inc.	Own	
63-2/ 830.6302	Color	47193401	Helm Agro US, Inc.	Own	
63-3/ 830.6303	Physical State	47193401	Helm Agro US, Inc.	Own	



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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 5/11/2012	EPA Reg No./File Symbol: 74530-23	Page 2 of 3			
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
63-4/ 830.6304	Odor	47193401	Helm Agro US, Inc.	Own	
63-5/ 830.7200	Melting Point	47170105	Helm Agro US, Inc.	Own	
63-7/ 830.7300	Density	47193401	Helm Agro US, Inc.	Own	
63-8/ 830.7840	Solubility	47193402 47170108	Helm Agro US, Inc.	Own	
63-9/ 830.7950	Vapour Pressure	47193403	Helm Agro US, Inc.	Own	
63-11/ 830.7550	Octanol/Water Partition Coefficient	47170106	Helm Agro US, Inc.	Own	
63-12/ 830.7000	pH	47193401	Helm Agro US, Inc.	Own	
63-13/ 830.6313	Stability	47170101	Helm Agro US, Inc.	Own	
63-14/ 830.6314	Oxidation/reduction: Chemical incompatibility	47170101	Helm Agro US, Inc.	Own	
63-16/ 830.6316	Explosibility	47170101	Helm Agro US, Inc.	Own	
63-17/ 830.6317	Storage Stability	47890801	Helm Agro US, Inc.	Own	
63-20/ 830.6320	Corrosion Characteristics	47890801	Helm Agro US, Inc.	Own	
N/A/ 830.7050	UV/Visible Adsorption	47193401	Helm Agro US, Inc.	Own	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

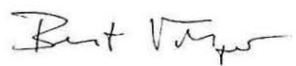


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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form
Approved
OMB No.
2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 3 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
81-1/ 870.1100	Acute Oral Toxicity - Rat	47170110	Helm Agro US	OWN	
81-2/ 870.1200	Acute Dermal Toxicity-Rabbit	47170111	Helm Agro US	OWN	
81-3/ 870.1300	Acute Inhalation Toxicity-Rat	47170112	Helm Agro US	OWN	
81-4/ 870.2400	Primary Eye Irritation-Rabbit	47170113	Helm Agro US	OWN	
81-5/ 870.2500	Primary Dermal Irritation-Rabbit	47170114	Helm Agro US	OWN	
81-6/ 870.2600	Dermal Sensitization in Guinea Pigs	47170115	Helm Agro US	OWN	
		EPA Company No			
	Generic Lambda-Cyhalothrin Data, offer to pay under "cite-all", see enclosed LOA from Syngenta dated 03/01/2011	100	Syngenta Crop Protection	Pay	
Signature 			Name and Title: Bert Volger, Ph.D. Agent for Helm Agro US, Inc.		Date May 11, 2012

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 256KUI35

Agency Tracking ID: 74311485542

Transaction Date and Time: 05/10/2012 10:40 EDT

Payment Summary

Address Information

Account Holder Name: Bert Volger
1087 Heartsease

Billing Address: Drive

Billing Address

2:

City: West Chester

State / Province: PA

Zip / Postal Code: 19382

Country: USA

Account Information

Card Type: Visa

Card Number: *****3785

Decision Number:

Registration Number: 74530-23

Helm Agro US

Company Name: Inc.

Company Number: 74530

Action Code: R340

Payment Information

Payment Amount: \$3,617.00

Transaction Date 05/10/2012
and Time: 10:40 EDT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 1 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	See submitted CSF
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	



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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 5/11/2012

EPA Reg No./File Symbol: 74530-23

Page 2 of 3

Applicant's/Registrant's Name & Address: Helm Agro US, Inc.
8275 Tournement Drive, Suite 340
Memphis, TN 38125

Product: Lambda-Cyhalothrin TC

Ingredient: Lambda-Cyhalothrin Technical

Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US, Inc.	Own	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form
Approved
OMB No.
2070-0060

Paper Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, D.C. 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/11/2012		EPA Reg No./File Symbol: 74530-23		Page 3 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournement Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
[REDACTED]	[REDACTED]	[REDACTED]	Helm Agro US	OWN	
		[REDACTED]			
		[REDACTED]			
	[REDACTED]	[REDACTED]	Syngenta Crop Protection	Pay	
Signature: <i>Bert Volger</i>			Name and Title: Bert Volger, Ph.D. Agent for Helm Agro US, Inc.		Date May 11, 2012



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 08, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CERES INTERNATIONAL LLC
HELM AGRO US, INC.
1087 HEARTSEASE DRIVE
WEST CHESTER, PA 19382

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 25-MAY-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

✓

Receipt for Section 3

S: 917574

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 74530 HELM AGRO US, INC.

V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 74530-23 Product Name: LAMBDA-CYHALOTHRIN TC

Override#:

Me Too
Section3: 100-1013

Me Too
Product Name: LAMBDA-CYHALOTHRIN TECHNICAL

Application Date: 11-May-2012



OPP Rec'd Date: 25-May-2012



Front End Date: 29-May-2012



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Study	
CSF	
<div> <div></div> <div></div> <div></div> </div>	

Fast Track: ☐

New Ingredient: ☐

View/Edit

Receipt Description:

Submission of PC data and CSF

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

48840500

Via Courier Delivery

May 11, 2012

Document Processing Desk (RD)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Mark Suarez
Registration Manager (PM -13)

Subject: Lambda-Cyhalothrin TC (EPA Reg.No.74530-23),
Amendment to registration: add an alternate source
Submission of PC data and CSF

Dear Mr. Suarez:

Helm Agro US Inc. is submitting this registration amendment for adding an alternate source to the current registration of Lambda-Cyhalothrin TC (EPA Reg. No. 74530-23). Based on the generated and enclosed product chemistry data (3 copies of each study report, see enclosed Bibliography of submitted studies), it has been demonstrated that the alternate source is very similar to the existing product (basic). There is no change in the manufacturing process. There is no significant change in the product's identity; actually there are fewer impurities than in the basic product, and the nominal concentration of the active ingredient has not changed.

To facilitate this application, enclosed you will find the following documents:

1. EPA Form 8570-1
Executed Application for an Amendment of Pesticide Registration (Form 8570-1; OPP Identifier # 269582).
2. Bibliography of Submitted Studies
List of submitted studies (transmission letter).
3. Study Data
Three copies of Product Chemistry and Batch Analysis reports (total of 2 volumes).
4. Confidential Statement of Formula
One copy of the alternate Confidential Statement of Formula (CSF).
5. Certification with Respect to Citation of Generic Data
An executed EPA form 8570-34 with respect to citation of data.

6. Data Matrix (EPA form 8570-35)

One copy of the Data Matrix of all previously submitted data in support of the proposed registration (one copy for Agency Internal Use, and one copy for Public File).

9. Registration Service Fee

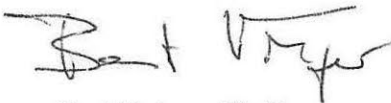
Under PRIA II, the subject application should be assigned EPA's Action Code R340: Application to add an alternate CSF; using a new technical source for Lambda-Cyhalothrin TC, that requires reviews within RD of product chemistry data of the new source (Non-fast track; EPA decision review time of 4 months, fee = \$3,617).

10. Confirmation of PRIA fee payment

Pay.gov Tracking ID: 256KUI35; Agency Tracking ID: 74311485542 (See attached copy of online payment confirmation).

We appreciate your expeditious processing of this submission and approval of the subject application. If you need any additional information or assistance regarding this application, please do not hesitate to contact me at 610-793-3222 (bertvolger@comcast.net).

Sincerely,

A handwritten signature in black ink, appearing to read "Bert Volger", with a stylized flourish at the end.

Bert Volger, Ph.D
Agent for
HELM Agro US, Inc.

Cc: Jan Stechmann -HAI

BIBLIOGRAPHY OF SUBMITTED STUDIES

Name and Address of Submitter: Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, TN 38125

Product(s): Lambda-Cyhalothrin Technical

EPA Registration No: 74530-23

Purpose of Submission: Submission of data in support of the application for an alternate CSF for Lambda-Cyhalothrin TC

Date of Submission: May 11, 2012

Volume Number	Study Title	Laboratory, ID Number	OPPTS Guideline Reference Number	EPA MRID Number (Reserved for EPA Use)
1 of 2	Lambda-Cyhalothrin TC Product Identity and Composition Description of Materials Used Description of Production Process Discussion of the Formation of Impurities Certified Limits Enforcement Analytical Method Submittal of Sample	HELM 120511	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800 & 830.1900	48840501
2 of 2	Analysis of Five Batches of Lambda-Cyhalothrin Technical Material with Associated Validation, in Compliance with Good Laboratory Practice (Preliminary Analysis)	David Norris Analytical Laboratories DNA1491	830.1700, 830.1750 and 830.1800	48840502

Memorandum

Date: 06/08/12

To: RM, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AND POLLUTION PREVENTION

OFFICE OF CHEMICAL SAFETY

Dr. Marshall B. Wixson
Helm Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125

Subject: Storage Stability and Corrosion Characteristics Studies
MRID Number: 478908-01
Product Name: Lambda Cyhalothrin TC
EPA Registration Number: 74530-23
Submission Date: October 20, 2009
Decision Number: 423157

Dear Dr. Wixson:

The Storage Stability (830.6317) and Corrosion Characteristics (830.6320) data submitted as conditional data in connection with the registration of 74530-23 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is **acceptable**.

If you have any questions regarding this action, please feel free to contact Carlyn Petrella by telephone at 1-703-347-0439 or via email at "petrella.carlyn@epa.gov".

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Insecticide Branch PM 10 Team Leader
Registration Division (7505P)
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: January 30, 2012

SUBJECT: Storage Stability and Corrosion Studies - Product Chemistry Review

FROM: Linda Mascall/Shyam Mathur
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Maggie Rudick/Kable Davis / PM 25
Richard Gebken / PM13
Registration Division (7505P)

Company Name / Number: HELM AGRO US, INC. / 74530

INTRODUCTION:

In support of previous applications, the company / applicant has submitted the one year Storage Stability and Corrosion Characteristics studies for the following products:

PM	Reg. Nos.	DP Barcodes	Decision Nos.	MRID Nos.	PC Codes
25	74530-43	389020	448092	484529-01	103601
13	74530-23	371547	423157	478908-01	128897

SUMMARY OF FINDINGS:

The Technical Review Branch has performed a fast track review of the associated products and concludes all of the studies are "acceptable". No products exhibited degradation of the active ingredient(s) in the products or corrosion of the packing material were observed during the period of testing.



HELM AGRO US, INC.

8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125
Phone: (901) 312-1525
Fax: (901) 312-1535
www.helmagro.com

478908-00

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard – South Building
2777 S. Crystal Drive
Arlington, VA 22202

10-20-2009

Attention: Ms. Kimberly Nesci PM#11

**RE: Storage Stability and Corrosion Characteristics Study for Lambda
Cyhalothrin TC (EPA Reg. # 74530-23)**

Dear Ms. Nesci:

Per your attached letter dated 2-18-2009, Helm is submitting the following in support of the registration of Lambda Cyhalothrin TC (EPA Reg. # 74530-23):

- 47890801
1. Your letter dated 2-18-2009.
 2. Storage Stability and Corrosion Characteristics of Lambda Cyhalothrin TC, 3 copies to satisfy OPPTS 830.6317 and OPPTS 830-6320.

Please do not hesitate to contact me if more information is needed or questions arise. I can be reached at 901-312-1525 or at mwixson@helmagro.com.

Sincerely:

Dr. Marshall B. Wixson Ph.D.
Manager Product Development
Helm Agro US, Inc.



U.S. ENVIRONMENTAL PROTECTION
AGENCY

Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

74530-23

Date of Issuance:

FEB 18 2009

Term of Issuance: Conditional

Name of Pesticide Product:

Lambda Cyhalothrin TC

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Helm Agro US, Inc.
8295 Tournament Drive, Suite 310
Memphis, TN 38125

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Submit the results of a one-year Storage Stability study, Guideline 63-17 (830.6317), and Corrosion Characteristics study, Guideline 63-20 (830.6320). It is required that the storage stability and corrosion characteristics observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in the electronic format and as well as a hard copy.
3. Submit the results of UV/Visible light absorption (830.750) and dissociation constant (830.7370) studies which are required to support the registration of this product.
4. Make the labeling changes listed below before you release the product for shipment:
 - a. Add the phrase "EPA Registration No. 74530-23".

Signature of Approving Official:

Kimberly Nesci
Product Manager II
Insecticide Branch
Registration Division (7505P)

*Dana R. Pilitt
for Kimberly Nesci*

Date:

FEB 18 2009

- b. Since the submitted dermal sensitization study was not acceptable, the following sentence must be added to the Hazards to Humans and Domestic Animals text: "Prolonged or frequently repeated skin contact may result in allergic reactions in some individuals." Based upon addition of this language, please note that resubmission of a dermal sensitization study for this product is not a condition of registration. However, should you elect to submit another dermal sensitization study, that submission would have to be in accordance with PRIA, including any associated fee.

- c. Revise the Hazards to Humans text to read as follows:

WARNING. May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and rubber gloves. Do not breathe dust or vapors. Wear a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P, or HE prefilter. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

- d. Revise the Environmental Hazards text to read as follows:

This pesticide is extremely toxic to fish and aquatic organisms and toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

- e. Include the label revisions for the Storage and Disposal section specified by PR Notice 2007-4, which is available at

www.epa.gov/opppmsd1/PR_Notices/pr2007-4.pdf.

- f. In the Directions for Use, in the crop listing for Terrestrial & Aquatic Food, revise "Com" to "Corn".

- g. In the Conditions of Sale revise "The Directions for Use of this product should be followed carefully." to read "The Directions for Use of this product must be followed carefully."

- h. In the Conditions of Sale add "To the extent permitted by applicable law," before the sentences beginning "All such risks shall be ...", "This warranty does not extend...", "HELM MAKES NO WARRANTIES...", and "THE EXCLUSIVE REMEDY..."
- i. In the Conditions of Sale, revise "In no event shall Helm or Seller be liable for any..." to read "To the extent permitted by applicable law, Helm or Seller shall not be liable for any..."

Submit three copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Material Sent for Data Extraction

Reg. # 74530-23

Description: _____

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 3/28/2013

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☒ Decision #: 47/494

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Melody Banks

Phone: 3055413 Division: IB/ID

Date: 3/27/2013

Material Sent for Data Extraction

Reg. # _____

Description: _____

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: _____

Phone: _____ Division: _____

Date: _____



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

FEB 28 2013

Bert Volger, Ph.D.
Agent for, HELM Agro US, Inc.
8275 Tournament Drive, Suite 340
Memphis, Tennessee 38125

Subject: Alternate Source/Confidential Statement of Formula
Lambda-Cyhalothrin TC
EPA Registration Number: 74530-23
Application Dated: October 29, 2012
Decision: 471494

Dear Dr. Volger:

The Confidential Statement of Formula, dated October 29, 2012, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, are acceptable.

This information has been added to our files for the product.

If you have any questions, please contact Melody Banks on 703 305-5413 or via E-mail @banks.melody@epa.gov.

A stamped copy of the product label is enclosed for your records.

Sincerely,

Mark Suarez

Insecticide Branch
Product Manager
Registration Division (7504P)

Enclosure: Copy of Product Chemistry Review



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: 408064; **REGISTRATION No.:** 74530-23; **PRODUCT NAME:** Lambda-Cyhalothrin TC; **DECISION No.:** 471494; **PC Code(s):** 128897; **ACTION CODE:** R340; **FOOD Use:** Yes

DATE: February 27, 2013

SUBJECT: Product Chemistry Review of Lambda-Cyhalothrin TC

FROM: David Lieu, Chemist
Inerts Ingredient Assessment Branch (IIAB)
Registration Division (7505P)

Julie Feb/27/2013

SBM 02/27/13

THROUGH: Shyam Mathur, Team Leader
Technical Review Branch (TRB)
Registration Division (7505P)

TO: Melody Banks / Mark Suarez, RM 13
Insecticide Branch
Registration Division (7505P)

DP BARCODE: 408064
DECISION NO.: 471494
REG. NUMBER: 74530-23
PRODUCT NAME: Lambda-Cyhalothrin TC
PC CODE: 128897
REGISTRANT: Helm Agro US, Inc.
USE: Insecticide
FOOD USE: Yes [X] No []
MRID NUMBERS: 489855-01 & 489855-02

DP BARCODE No.: 408064; **REGISTRATION No.:** 74530-23; **PRODUCT NAME:** Lambda-Cyhalothrin TC;
DECISION No.: 471494; **PC Code(s):** 128897; **ACTION CODE:** R340; **FOOD Use:** Yes

Table of Contents

INTRODUCTION:.....	3
SUMMARY OF FINDINGS:	3
CONCLUSIONS:.....	4
830.1550: Product identity	5
830.1600: Description of starting materials	7
830.1620: Description of production process	8
830.1670: Discussion on the formation of impurities	17
830.1700: Preliminary analysis	18
830.1750: Certified limits	24
New alternate CSF	26
Basic CSF	27

INTRODUCTION:

The registrant has submitted an application to amend the registration for the subject product by submitting a new alternative CSF (dated October 29, 2012) with nominal concentration of 96.2%. The basic CSF (dated June 28, 2007) indicates Helm AG, Nordkanalstrasse 28, 20097 Hamburg Germany as the production site with nominal concentration of 97.9% which is also the product label claim nominal concentration. To support the new alternative CSF the registrant has submitted group A product chemistry data with MRID Nos. 489855-01 and -02. TRB has been asked to determine the acceptability of the new alternate CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. The registrant has submitted a new Confidential Statement of Formula for an alternative formulation (dated October 29, 2012) for Lambda-Cyhalothrin TC. The nominal concentration of the active ingredient is 96.2%, based on the five batch analysis. The product label claim nominal concentration for the technical is 97.9%. The registrant has reported [REDACTED] impurities which included one impurity of toxicological significance at the same concentrations as in the current basic CSF. The data submitted satisfy the data requirements of 40CFR§158.320 [MRID No. 489736-01].
2. The product chemistry data submitted corresponding to guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (description of formation of impurities), and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.320, §158.325, §158.330, §158.340 and §158.350 [MRID Nos. 489736-01 & 489736-03].
3. The five batch analysis was performed at Nutrichem Laboratory Co. Ltd. in compliance with 40 CFR§160 on Good Laboratory Practice. The five representative batches were assayed by GC-FID and MS with internal standard quantification method for the active ingredient, lambda-cyhalothrin. The [REDACTED] were identified and quantified by HPLC-UV (225 nm) using external standard technique. The [REDACTED] was identified and quantified by GC-MS with internal standard quantification method. The data submitted corresponding to the guideline reference 830.1700 (preliminary analysis, five batches) satisfy the data requirements of 40CFR§158.345 [MRID No. 489736-02].

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CONCLUSIONS:

The TRB has reviewed the new alternate CSF and the supporting group A product chemistry data and has concluded that:

1. The new CSF for the alternate formulation (dated October 29, 2012) is substantially similar in chemical composition to the current basic CSF (dated June 28, 2007) and is acceptable. There is slight difference in the nominal concentration of the active ingredient (97.9% in current basic & label claim vs 96.2% in new alternate CSF) however this falls within the upper and lower limits set in the basic CSF.
2. The registrant has listed [REDACTED] new major impurities in the proposed alternate CSF that is not found on the basic CSF (dated June 28, 2007). According to Dr. Byron Backus (toxicologist in TRB), the presence of these additional impurities in the concentrations provided on the CSF will not cause any adverse health and/or environmental effects based on their chemical structures. The impurities are considered as not of toxicological concern.
3. The product chemistry data submitted corresponding to guidelines 830.1550 (product identity & composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (description of formation of impurities), 830.1700 (preliminary analysis) and 830.1750 (certified limits) are acceptable.

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DP BARCODE No.: 408064; REGISTRATION No.: 74530-23; PRODUCT NAME: Lambda-Cyhalothrin TC;
DECISION No.: 471494; PC Code(s): 128897; ACTION CODE: R340; FOOD Use: Yes

830.1550: Product identity: (MRID No. 489855-01)

Trade Name:	Lambda-Cyhalothrin TC
Alternate Brand Name:	Lambda-Cyhalothrin Technical
Synonyms	R119321, PP321
EPA Registration No.:	74530- to be assigned
PC Code	128897
Source:	Alternate, [REDACTED]
Common name (ISO):	Lambda-cyhalothrin (technical); ISO # 1750 (approved)
Chemical Name (IUPAC):	A reaction product comprising equal quantities of (S)- α -cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (R)- α -cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate
CAS Nomenclature:	[1a(S*),3a(Z)]-(\pm)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate
CAS Number:	91465-08-6
Molecular Weight	449.9
Identity test	GC (relative retention time), NMR, IR
Empirical Formula	C ₂₃ H ₁₉ ClF ₃ NO ₃
Structural Formula	
Purpose	Insecticide for Formulation Purposes only
Nominal Concentration / Label claim of active ingredient:	97.9% w/w

Product ingredient source information may be entitled to confidential treatment

Table 1. Manufacturing and Impurity Data for Lambda-cyhalothrin TC.				
GLN	Requirement	MRID	Status	Details and/or Deficiency
830.1550	Product Identity & Composition	489855-01	A	The registrant has submitted a alternative CSF (dated October 29, 2012) with nominal concentration of 96.2% for the AI, which agrees with the product label claim nominal concentration.
830.1600	Description of materials used to produce the product	489855-01	A	The registrant has provided MSDS's for all the starting materials used in the production of Lambda-Cyhalothrin TC.
830.1620	Description of production process	489855-01	A	The Lambda-Cyhalothrin TC is produced in [REDACTED] steps. Details of the each steps of the process have been submitted. The quality assurance steps taken have been provided.
830.1670	Discussion on the formation of impurities	489855-01	A	The registrant has listed [REDACTED] impurities on the alternative CSF as identified during the 5 batch analysis. The origin and mechanisms of their formations have been discussed. None of the impurities identified are of tox concern.
830.1700	Preliminary analysis	489855-02	A	The AI and impurities have been identified in the 5 batches of Lambda-Cyhalothrin TC by GC-MS/FID and HPLC/UV method with internal and external standard quantification. The structures of the AI & the impurities have been confirmed by GC-MS methods. The analytical methods have been validated for precision, linearity and accuracy.
830.1750	Certified limits	489855-01 489855-02	A	The certified limits of AI and impurities are based on the five bath analysis.
830.1800	Enforcement analytical method	489855-01 489855-02	A	The validated analytical method used during the 5 batch analysis is applicable for enforcement purposes.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 10/29/2012		EPA Reg No./File Symbol: 74530-23		Page 1 of 3	
Applicant's/Registrant's Name & Address: Helm Agro US, Inc. 8275 Tournament Drive, Suite 340 Memphis, TN 38125		Product: Lambda-Cyhalothrin TC			
Ingredient: Lambda-Cyhalothrin Technical					
Guideline Reference Numbers, OPP/OPPTS	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1/ 830.1550	Product Identity and Composition	47170101 48840501	Helm Agro US, Inc.	Own	
61-2/ 830.1600 & 830.1620	Beginning Materials and Manufacturing Process	47170101 48840501	Helm Agro US, Inc.	Own	
61-3/ 830.1670	Discussion of the Formation of Impurities	47170101 48840501	Helm Agro US, Inc.	Own	
62-1/ 830.1700	Preliminary Analysis	47170102 48840502	Helm Agro US, Inc.	Own	
62-2/ 830.1750	Certified Limits	47170101 48840501	Helm Agro US, Inc.	Own	See submitted CSF
62-3/ 830.1800	Enforcement Analytical Method	47170103 48840502	Helm Agro US, Inc.	Own	
63-2/ 830.6302	Color	47193401	Helm Agro US, Inc.	Own	
63-3/ 830.6303	Physical State	47193401	Helm Agro US, Inc.	Own	